DETAILED ACTION

Applicant's arguments, filed 1/14/2011, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1 and 5-13 under 35 U.S.C. 103(a) as being unpatentable over US 20030082232 ('232) in view of Widder (European Journal of Cancer and Clinical Oncology, 1983) is maintained.

Applicant argues that paragraph 71 of '232 is directed to calcium phosphate only, and not calcium sulfate. Paragraph 71 teaches that it may be desirable to combine magnetic materials with calcium phosphate. It does not teach that it may be desirable to combine magnetic materials with calcium sulfate.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner agrees with Applicant that paragraph 71 states "calcium phosphate" (specifically “calcium phosphate adjuvant”) and does not state "calcium sulfate". The question at hand is what the ordinary artisan would take from paragraph 71 in view of the larger context of ‘232. ‘232 discloses a calcium-containing adjuvant and vaccine delivery vehicle which, when present alone or in combination with one or more active agents such as antigens or vaccines, elicits a host response or augments a host response towards the antigen or vaccine (paragraph 23). The calcium containing adjuvant preferably comprises calcium phosphate or calcium sulfate (paragraphs 24-25). Although both calcium phosphate and calcium sulfate are clearly preferred, the examples of ‘232 are directed to calcium phosphate, and throughout much of the disclosure of ‘232, “calcium phosphate adjuvant" is recited as a synonym of "calcium-containing adjuvant". One such place is paragraph 71, which recites “calcium phosphate adjuvant”. Thus, the skilled artisan would understand that the recitation of “calcium phosphate adjuvant” is not limited to calcium phosphate alone, but "calcium phosphate adjuvant" is a synonym for "calcium-containing adjuvant". As calcium sulfate is a preferred calcium-containing adjuvant (paragraph 25), the ordinary artisan would reasonably apply the teaching of paragraph 71, i.e. that magnetic particles may be added, to embodiments of the invention where the calcium-containing adjuvant is calcium sulfate. In summary, '232 treats “calcium phosphate adjuvant” and “calcium-containing adjuvant" as synonyms, and thus paragraph 71 would prompt the ordinary artisan to add

magnetic particles to the “calcium phosphate adjuvant", i.e. the "calcium-containing adjuvant", of which calcium sulfate is a preferred component.

New Grounds of Rejection

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of “a few days” is unclear. The term "a few" is a relative term. This term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the term. Does “a few” mean 3, 10, 20, etc?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6-8, and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 6236804 (JP '804; English translation provided). JP '804 teaches a biocompatible degradable composite comprising a biocompatible degradable calcium sulfate matrix, said matrix containing pulverized magnetic particles (pages 3-4). The composite is initially granular, and the granular mixture is kneaded with water to become a paste and subsequently hardened (page 4, first full paragraph). It is the granular mixture that anticipates the instant claims. Although JP '804 does not appreciate that its pulverized magnetic particles comprise particles between 0.001 microns to 10 microns as required by instant claim 1, nor the narrower ranges required by instant claims 10-11 and 23, due to particle distributions inherent in pulverized materials, there must at least be two particles in the pulverized magnetic particles within the particle size range of 0.001 microns to 10 microns. The Examiner interprets "wherein the magnetic particles have a particle size between 0.001 microns to 10 microns" in instant claim 1 to require at least two magnetic particles be present in a particle size range of 0.001 microns to 10 microns. The language of claim 1 is such that not all of the magnetic particles present must be within this particle range, as the claim uses open language to describe the components of the material (i.e.

comprising), and the particle size range is not an average particle size range. For the reasons stated above, it is reasonable that the pulverized magnetic particles of JP '804, although having particles outside this range, must at least comprise two particles within the range of between 0.001 microns to 10 microns (claim 1). Similarly, the particle distribution inherent in the pulverized magnetic particles of JP '804 would also reasonably comprise at least two particles between 0.001 microns to 0.1 microns (claim 10), between 0.1 microns to 10 microns (claim 11), and between 0.05 microns to 0.1 microns (claim 23).

The recitation in instant claim 1 "…said material being found as a slurry during its introduction into an organism, as a solid subsequently, and said matrix being resorbed within a period of eight weeks" is an intended use limitation. The recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the biocompatible degradable composite material of JP '804 is structurally identical to that of the instant invention, in that it comprises a degradable biocompatible calcium sulfate matrix, said matrix containing magnetic particles wherein the magnetic particles have a particle size between 0.001 microns to 10 microns. A composition cannot be separated from its properties. As the material of JP '804 is structurally identical to that of claim 1, it must inherently be capable of performing the intended use of claim 1, that is, to be found as a slurry during

its introduction into an organism, as a solid subsequently, said matrix being resorbed within a period of eight weeks.

The magnetic particles of JP '804 may comprise iron (page 5, second paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a

later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20030082232 ('232) in view of Widder (European Journal of Cancer and Clinical Oncology, 1983). '232 discloses a biocompatible degradable composite material (abstract), characterized in that it comprises a calcium-containing adjuvant, preferably calcium sulfate, (paragraph 25), said matrix containing magnetic particles (paragraph 71), said material being found as a slurry during its introduction into the organism, as a solid subsequently (paragraphs 91-92) and said matrix being resorbed within a period of one month or less (paragraph 28). The material may additional comprise collagen (see paragraph 43) and polylactic and polyglycolic acids (paragraph 67). The matrix has biocompatibility and degradation characteristics compatible with applications of the material for treating bone tumors (paragraph 71). The matrix comprises particles coated with a calcium phosphate layer containing a fluorescent element to measure the adjuvant's binding capacity with an antigen (paragraph 85).

'232 fails to disclose magnetic particle diameters of between 0.001 microns to 10 microns or between 0.05 microns to 0.1 micron. '232 fails to teach ferrite magnetic particles. '232 fails to teach a resorption time of a few days to four weeks.

'232 incorporates by reference Widder as examples of magnetic particles that may be incorporated into its composition (paragraph 71). Widder discloses

magnetically response albumin microspheres to treat tumors (abstract). The microspheres comprise iron in the form of magnetite, a ferrimagnetic mineral (Examples). The exemplified microspheres have an average diameter of about 1 micron (abstract; Examples).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to incorporate the microspheres of Widder into the composition of '232, to treat tumors, as this is one embodiment of the invention taught by '232. The microspheres have an average diameter of about 1 microns which anticipates 0.1 to 10 microns (instant claim 11). This is an average diameter, however, and due to particle size distribution inherent in microparticle formulations, it is reasonable that at least some portion of the microparticles have diameters between 0.001 to 0.1 microns. It would have been obvious to choose europium as the fluorescent element of '232, as this is a common fluorescent element used in measuring binding capacity. It would have been further obvious to find the resorption time of a few days to a four weeks, as this overlaps with the resorption time taught by '232 of "less than one month". "'[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" MPEP § 2144.05, II.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL G. HARTLEY/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
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